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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,432	06/04/2001	Seth P. Finklestein	00786-400002	4601

7590 10/25/2002  
Fish & Richardson  
225 Franklin Street  
Boston, MA 02110-2804

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/25/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/762,432

Applicant(s)

FINKLESTEIN, SETH P.

Examiner

Olga N. Chernyshev

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6, 17, 18 and 25-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 17, 18 and 25-43 is/are rejected.
- 7) ☒ Claim(s) 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 7-16 and 19-24 have been cancelled, claim 1 has been amended and claims 25-43 have been added as requested in the amendment of Paper No. 10, filed on August 19, 2002. Claims 1-6, 17-18 and 25-43 are pending in the instant application.
2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on August 19, 2002 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Objections***

5. Claim 38 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 38 depends from claim 37, which encompasses a method for reducing a focal ischemic episode by administration of EGF, while claim 38 recites a global ischemic episode. These two limitations appear to be mutually exclusive. Appropriate correction is required.

*Claim Rejections - 35 USC § 103*

6. Claims 1-6, 17-18 and 25-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds et al. (WO 98/221127, May, 1998) in view of Peng et al. (April, 1998, J. Cerebral Blood Flow and Metabolism, 18, pp.349-360) for reasons of record as applied to claims 1-6 and 14-18 in section 3 of Paper No. 8.

Applicant traverses the rejection on the premises that “neither Reynolds nor Peng suggest administration of EGF more than six, 12, or 24 hours after an injury to the CNS” (see page 6, fourth paragraph of the Response). This has not found to be persuasive for the following reasons.

As it is stated in the publication of Peng et al. “Cerebroventricular infusion of EGF (24 or 120 ng/d) for 7 days to gerbils starting 2 hours before or immediately after transient forebrain ischemia caused a significant prolongation of response latency time in a passive avoidance task in comparison with the response latency of vehicle treated ischemic animals” (see abstract of the document). Thus, according to Peng et al, administration of EGF started 2 hours before or immediately after the injury to the central nervous system and lasted for 7 days after the injury. The administration of EGF, as concluded in Peng et al. publication, led to reduction of a neurological deficit, which resulted from the injury to the central nervous system. While it is true that administration of EGF in experiments of Peng et al. did not commence 6, 12 or 24 hours after the injury, it continued during and long after these particular time points. There are no teachings in the prior art that would suggest that the established neuroprotective action of EFG is only effective when administered before or immediately after the trauma. There is no basis for concluding that the central nervous system would be refractive to the action of EGF after an injury to the CNS occurred. Publication of Peng et al. suggests that “EGF has a neuroprotective

Art Unit: 1646

effect on ischemic hippocampal neurons *in vivo* possibly through inhibition of free radical neurotoxicity and lipid peroxidation” (see the abstract). There is no scientific evidence to support the conclusion that such effect is only achieved by administration of EGF before free radical neurotoxicity and lipid peroxidation occur. Therefore, based on the publications of Peng et al. and Reynolds et al., one of ordinary skill in the art would reasonably conclude that EGF has a neuroprotective effect, which reveals in reduction of a neurological deficit during and after an injury to the central nervous system.

Moreover, because a neuroprotective effect of EGF has been established, one of ordinary skill in the art would readily appreciate the obvious advantage to use EGF to treat an injury to the central nervous system any time after the injury rather than before, unless one can predict when such injury is going to take place and be able to administer EGF before time. One of ordinary skill in the art would be motivated to administer EGF to a patient with a trauma to the nervous system as soon as possible within up to 7 days after the injury in order to achieve a beneficial action of EGF.

Reynolds et al. discloses methods for protecting neural tissue from the effects of insult, and neurological diseases or disorders by administering growth factors (EGF in particular) to the neural tissue of a mammal (see the abstract, also page 4, line 2, Example 2 on page 12 and claims 11-15). Neurodegenerative diseases, which intended to be treated by methods of Reynolds et al. include stroke and physical trauma to the central nervous system (page 1, lines 9 and 14). The document of Reynolds et al. teaches exogenous administration of EGF for such treatment (page 4, lines 9-13 and pages 8-9). Reynolds et al. do not expressly disclose a method of administration of EGF for reducing a neurological deficit in a patient with an injury to the CNS wherein

Art Unit: 1646

administration of EGF commences more than 6, 12 or 24 hours after the injury (claims 14-16 of the instant application).

### *Conclusion*

7. No claim is allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the

Art Unit: 1646

organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.  
October 25, 2002

OC



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800